

Hepatitis C 2016, CSTE*

Interpretation of Laboratory Reports

Hepatitis C Criteria for Case Diagnosis and Classification*

Acute Hepatitis C

Clinical Criteria

An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, abdominal pain) AND either a) jaundice, OR b) elevated serum alanine aminotransferase (ALT) levels >200 IU/L, during the period of acute illness.

Laboratory Criteria for Diagnosis

- A positive test for antibodies to hepatitis C virus (anti-HCV)
- Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)

Criteria to Distinguish a New Case from an Existing Case

A new acute case is an incident acute hepatitis C case that meets the case criteria for acute hepatitis C and has not previously been reported.

Case Classification

Probable

- A case that meets clinical criteria and has a positive anti-HCV but has no positive confirmatory HCV tests AND
- Does not have test conversion within 12 months or has no report of test conversion

Confirmed

- A case that meets clinical criteria and has a positive confirmatory HCV test OR
- A documented negative HCV antibody or confirmatory HCV test followed within 12 months by a positive result of any of these tests (test conversion).

Chronic Hepatitis C

Clinical Description

Most hepatitis C virus (HCV)-infected persons are asymptomatic; however, many have chronic liver disease, which can range from mild to severe.

Laboratory Criteria for Diagnosis

One or more of the following two criteria:

- A positive test for antibodies to hepatitis C virus (anti-HCV)
- Nucleic Acid Test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)

Criteria to Distinguish a New Case from an Existing Case

Case Classification

Probable

- A case that does not meet clinical criteria and has no report of clinical criteria AND
- Does not have test conversion within 12 months or no report of test conversion AND
- Has a positive anti-HCV but has no positive confirmatory HCV tests

Confirmed

- A case that does not meet clinical criteria and has no report of clinical criteria AND
- Does not have test conversion within 12 months or no report of test conversion AND
- Has a positive confirmatory HCV test (s)

What is a Screening Test?

Hepatitis C antibody results mean that hepatitis C antibodies were found in the blood and a client has been infected with Hepatitis C at some point in time. Results may be reported as:

- Positive
- Reactive
- Highly reactive
- Strongly reactive

What is a Confirmatory Test?

Hepatitis C confirmatory test methods describe the viral load a client has and determines how infectious they are. "Viral load" is the amount of virus a person has in his or her body for a specific condition. Any positive RNA, NAT, or PCR result indicates active hepatitis C infection.

The genotype test tells the physician what type of treatment may be best for a person infected with the hepatitis C virus. Some individuals may be infected with more than one genotype at a time.

Hepatitis C Screening Test Names

- Hepatitis C Antibody
- Hepatitis C Antibody by EIA
- Hepatitis C Antibody by CHLIA
- Hepatitis C Ab
- Hepatitis C Virus Ab
- Hepatitis C Virus Ab IgG
- Hep C Ab
- Hep C Ab QL
- Hep C IgG
- HCV Ab
- HCV Ab Screen
- Anti-HCV
- Signal to Cut Off Ratio

Hepatitis C Confirmatory Test Names

- HCN QN bDNA (RNA)
- HCV Ab Confirmation
- HCV Amplification
- HCV ELUT: Singlet (NAT)
- HCV Genotype
- HCV Genotype by Sequencing
- HCV Genotype Lipa
- HCV Genotype SerPI PCR
- HCV NAT
- HCV PCR
- HCV Qual
- HCV RNA
- HCV RNA (International Units)
- HCV RNA Detect/Qual
- HCV RNA PCR
- HCV RNA Qnt Real-time PCR
- HCV RNA Quant
- HCV RNA Quant by PCR
- HCV RNA Quant by PCR, interp
- HCV RNA SerPI PCR- Log IU
- FibroSURE
- HCV Subtypes
- Hep C Ab Supplemental
- Hep C QN PCR
- Hep C Quant (IU/mL)
- Hep C SerPI QL PCR
- Hep C Viral RNA QN
- Hepatitis C Quantitation
- Hepatitis C Virus RNA
- Hepatitis C Virus RNA Qual PCR
- Heptimax HCV RNA

Lab Tests Commonly Used by Blood and Plasma Centers

Lab Test Name	Lab Test Type	Where Test is Used (Provider)
HCV ANTIBODY BY CHLIA	Screen	Blood Centers (e.g.; American Red Cross)
HCV ANTIBODY BY EIA	Screen	Blood Centers (e.g.; American Red Cross)
DHCV NAT	Confirmatory	Blood Centers (e.g.; American Red Cross)
HCV NAT AMPLISCREEN	Confirmatory	Blood & Plasma Centers
NHCV	Confirmatory	Blood Plasma Centers (e.g., Saturn Biomedical)
HCV VM, PCR	Confirmatory	Blood Plasma Centers
ULTRIO Assay	Confirmatory	Blood Plasma Centers

Blood and Plasma

Blood is used for transfusions, during chemotherapy treatments, to have on hand for emergency purposes, etc. Plasma is used for the creation of treatments (immunological disorders, wound healing), therapies (treatment of bleeding disorders, shock and burns), and other therapeutic formulations.

FibroSURE

FibroSURE testing makes an assessment of liver status following a diagnosis of hepatitis C. It determines the baseline status of the liver before initiating HCV therapy, and is used for post-treatment assessment of liver status six months after completion of therapy. FibroSURE can also be used for a noninvasive assessment of liver status in patients who are at increased risk of complications from a liver biopsy.

NOTE: If unsure about whether or not a lab test is for hepatitis C screening or confirmatory, please consult the lab testing facility or Indiana State Department of Health (ISDH). The Health Department contact number is **317.233.7125**